

ORAL PRESENTATION

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Long-term post-trial follow-up of participants in randomised trials: lessons learned from the mrc / bhf heart protection study (HPS)

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Introduction

Treatment effects may be significantly underestimated by analyses restricted to the relatively brief intervention phase of a randomised trial, and effects on cancer may only emerge during prolonged follow-up. In HPS, post-trial follow-up for non-fatal events was largely achieved via annual postal questionnaires, and the methods used may help inform the design of subsequent similar studies.

Methods

20,536 patients at increased vascular risk were randomly allocated 40 mg simvastatin or placebo for a mean "in-trial" duration of 5.3 years. Post-trial follow-up of all 17,519 surviving participants yielded a mean total follow-up of 11.0 years, with non-fatal events and statin use reported by participants in annual mailed questionnaires or via GPs, supplemented with cause-specific mortality and site-specific cancer incidence via central registries.

Results

Response rates to annual postal questionnaires were around 80% each year and total 34,555 non-fatal events were reported. Number of events reported from different sources showed: 24,691 from questionnaire, 6162 from cancer registries, 3400 via GPs, 239 from letters/phone calls and 63 from non-fatal events on death certificate. Based on these large numbers of fatal and non-fatal events, long-term follow-up of HPS reliably demonstrates the long-term efficacy and safety of lipid-lowering statin therapy.

Conclusion

Capturing non-fatal post-trial events via postal questionnaires is effective, and allows reliable assessment of the benefits and potential hazards of the intervention being studied. However, the process was labour-intensive, and follow-up via Hospital Episode Statistics (HES) data may be an alternative cost effective means of comprehensively gathering such data in future studies.

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